



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,465	07/03/2003	Patrick Hettrich	1/1159-1-C1	4938

28501 7590 06/06/2005

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER

GORMAN, DARREN W

ART UNIT PAPER NUMBER

3752

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No.	Applicant(s)	
	10/613,465	HETTRICH ET AL.	
	Examiner	Art Unit	
	Darren W Gorman	3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on October 28, 2000. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "16" has been used to designate both the riser and area surrounding the pressure control valve in Figure 2. The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "27" has been used to designate both the push-on cap covering the nozzle and the opening into the lower area of the riser in Figure 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

Reference number "29" on Figure 1 is not disclosed in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

5. The specification is objected to since none of the above section headings are included in the specification of the present application. In addition, content corresponding to several

Art Unit: 3752

sections headings, for example the "BREIF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS" has been omitted from the specification.

6. The disclosure is further objected to because of the following informalities:

On page 5, line 18, two different elements (the opening into the riser and the upper area of the riser) have been designated with the same reference number "26".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claim 1, the use of the words "and/or" renders the claims ambiguous when referring to the locations of the oligodynamically-effective substances within the atomizer.

Further regarding claim 1, the phrase "for example", or in this case "i.e." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

10. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

Art Unit: 3752

does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 2-4 recite broad recitations in terms of external diameters, internal diameters, and wall thickness respectively, and the claims also recite more narrow limitations of those recitations within the same respective claims.

11. The term "about" in claims 9-11 is a relative term, which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Because of the large range of the bottle height claimed, one skilled in the art would not be able to determine the metes and bounds of the claimed invention.

Art Unit: 3752

12. The above noted informalities are merely exemplary and are not to be taken as an exhaustive list of all such instances. Therefore, Applicant should review the claims in their entirety for compliance with 35 U.S.C. § 112, second paragraph.

For the purpose of this office action, the claims will be examined as best understood by the examiner.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-4, 7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geimer, USPN 6,053,368.

With regard to claims 1 and 7, Geimer discloses a sterile dispensing apparatus for fluids, including pharmaceutical fluid, which fluid is not under pressure, comprising a storage container (1) in the shape of a bottle for the fluid, wherein the storage container has a beading on the upper end of the bottle neck (no reference number – see figure 1) and an upper edge which is depicted in figure 1 as being ground flat. Geimer also discloses a pump attachment (2), fitted permanently to the neck of the storage container for manual atomization of the fluid by pumping. Geimer discloses that the pump attachment has a snap closure (no reference number – see figure 1) for fixing the pump attachment onto the storage container, a pump channel (no reference number –

Art Unit: 3752

see figure 1) which can pump fluid from the storage container into a pressure chamber (4), a ball valve (5) which is provided between the storage container and the pressure chamber, a riser (7, 21) which leads from the pressure chamber to a nozzle (23), a pressure control valve (22) which is operably connected to the riser, a nozzle (23) to atomize the fluid, a triggering element (20) via which a piston (3) can be operated to produce the pressure necessary for atomization in the pressure chamber, air inlet points (no reference number – see figure 1) outside of the riser and air inlet paths (26) extending from outside the pump attachment into the storage container, oligodynamically-effective substances in and along the paths taken by the fluid in the pump channel and riser between the storage container and the nozzle (see column 3, lines 22-28), and sterilization means (25) along the path taken by the inflowing air (see figure 1, and column 3, lines 29-44).

Geimer, however does not disclose the fluid storage container as being made of aluminum.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the storage container from aluminum, tin, or any other light, yet durable metals or metal alloys in order to make the container non-breakable for potential safety concerns and lightweight for portable convenience, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

With regard to claims 2-4 and 9-11, Geimer discloses all of the claimed elements of claim 1, as discussed above, however Geimer does not disclose exact measurements or measurement

Art Unit: 3752

ranges with regard to the external diameter of the bottle neck, internal diameter of the bottle neck, thickness of the bottle wall and bottle neck and base areas, or bottle height.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the dimensions of the bottle wall within a thickness range that would allow the bottle to be impermeable to possible contamination, make the internal and external dimensions of the bottle neck within a range that is suitable for easily and effectively attaching the pump assembly, and make the height of the bottle of a size that would render the apparatus lightweight, portable, and easy to store. These particular ranges can be determined by routine experimentation in order to optimize the spray function of the atomizer and do not represent a patentable departure from the teachings of Geimer.

15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geimer, in view of Nagel, USPN 5,988,413.

Geimer discloses all of the claimed elements of claim 1, as discussed above, however Geimer does not disclose an annular indentation on the bottle neck extending perpendicular to the axis.

Nagel discloses a container with a closure assembly, which uses an annular indentation at the container neck (see figure 7, and column 8, lines 3-16), which extends perpendicular to the axis of the container for securing and locking a cap.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an annular recess, such as taught by Nagel, with the atomizer of Geimer, in order to include an option for securing and locking a closure cap.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geimer, in view of Hollenberg, DE 197 31 911 A1.

Geimer discloses all of the claimed elements of claim 1, as discussed above, however Geimer does not disclose that the storage container, including the neck and the upper edge of the neck, are varnished on the inside.

Hollenberg discloses a perfume atomizer with a metal storage container (2) wherein during the assembly process, the container is filled with an alcohol resistant varnish and emptied after the varnish has filled all gaps in the container and formed an inner lining (5) to make the atomizer completely leak proof (see English translation of Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form an inner lining of varnish, such as taught by Hollenberg, in the liquid storage container of Geimer, in order to make the container leak proof and corrosion resistant.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Geimer, in view of Henneman, USPN 6,244,472.

Geimer discloses all of the claimed elements of claim 1, as discussed above, however Geimer does not disclose a seal made from rubber, or natural or synthetic caoutchouc, or polyethylene, that is disposed between the bottle neck and the pump attachment.

Hennemann discloses a sterile pump dispenser that is usable with pharmaceutical fluids with a leak-proof seal (62) made of silicone (synthetic rubber), polyethylene, or polypropylene,

Art Unit: 3752

or a mixture thereof, which is disposed between the bottle neck (no reference number) and the pump attachment (4) (see figure 2, and column 4, lines 24-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a seal, such as the one taught by Hennemann, between the bottle neck and the pump attachment of Geimer, in order to create an bacteria-impermeable, leak-proof, yet resilient seal to prevent contamination of the liquid within the storage container.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US patents to Ruscitti et al., Schuetz, Ryder et al., Geimer, and Bommer et al. disclose various arrangements of liquid pump dispensers/atomizers that have bacterial filter control and/or use oligodynamically-effective substances for maintaining the device in a sterile condition.

19. This is a Continuation of applicant's earlier Application No. 10/001,527. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 3752

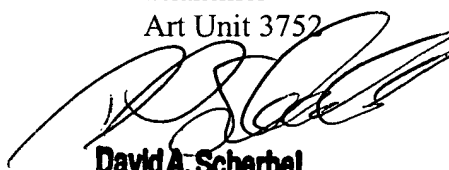
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darren W Gorman whose telephone number is 571-272-4901. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Scherbel can be reached on 571-272-4901. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DWG 5/20/05
DWG
May 20, 2005

Darren W Gorman
Examiner
Art Unit 3752

David A. Scherbel
Supervisory Patent Examiner
Group 3700